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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,387	02/13/2002	Harry Flewitt	C70376	1701

20462 7590 08/27/2003

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EXAMINER

PICKETT, JOHN G

ART UNIT	PAPER NUMBER
3728	9

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NY

Office Action Summary	Application No.	Applicant(s)
	09/890,387	FLEWITT, HARRY
	Examiner Greg Pickett	Art Unit 3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 June 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 16 and 18-30 is/are pending in the application.

 4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 16 and 18-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 02 June 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

 1. Certified copies of the priority documents have been received.

 2. Certified copies of the priority documents have been received in Application No. _____.

 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s). _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

1. This Office action acknowledges the applicant's Amendment B, presented as Paper No. 8. Claims 16 and 18-30 are pending in the application.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

3. In light of the applicant's amendment, the objection to the drawings is hereby withdrawn.

Specification

4. In light of the applicant's amendment, the objection to the specification is hereby withdrawn. The examiner notes the inclusion of the Abstract in Amendment B.

Claim Objections

5. In light of the applicant's amendment, the objection to claims 26-28 is hereby withdrawn.

Claim Rejections - 35 USC § 112

6. The rejection of claim 17 under 35 U.S.C. 112, first paragraph, is rendered moot by its cancellation.

7. In light of the applicant's amendment, the rejection of claims 16-30 under 35 U.S.C. 112, second paragraph, is hereby withdrawn.

Claim Rejections - 35 USC § 102

8. In light of the applicant's amendment, the rejection of claims 16, 20, and 30 under 35 U.S.C. 102(b), is hereby withdrawn.

Claim Rejections - 35 USC § 103

9. Claims 16, 20, and 30 are rejected under 35 U.S.C. 103(a) as being anticipated by Meshberg (US 5,516,006) in view of Simmons (US 5,788,076).

Regarding claim 16, Meshberg discloses container 10 with base wall 34, side-walls 36 and 37 extending upwardly from the base wall (Figure 1, rotated 180°) toward upper mouth opening 15. Side-walls 36 and 37 are spaced apart inner wall 36 and outer wall 37, and are made of plastic material (Col. 4, In 38-39). Meshberg anticipates a conventional decorative casing for the device (Col. 4, In 32-34). Meshberg further anticipates an internal cavity containing a medicament content (Col 4, In 19-22) and being bounded in part by inner wall 36. Base wall 34 is continuous circumferentially and links inner wall 36 and outer wall 37, closing the space between them.

Meshberg does not expressly disclose a label located on a part of the outer wall, the inner surface of said part not in contact with the medicament content.

Simmons discloses a container label 3 for a container 2 which wraps around the entire outer sidewall of the container (see Figure 2). Simmons teaches the label use for promotional purposes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the container of Meshberg with a label as taught by Simmons in order to promote the sale of the product. As such, the outer label of Meshberg-Simmons would cover the parts of the outer wall in which the inner surface of said part are not in contact with the medicament content.

As to claim 20, Meshberg discloses lower part 32 and upper part 14 fitting together with a seal (Figure 1) with upper inner wall 16 and upper outer wall 31.

As to claim 30, Meshberg discloses a nasal dispenser with means 13 to deliver its medicament content to the nasal area of the user.

10. Claims 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meshberg in view of Simmons and Henkel et al. (WO 98/14189).

Meshberg-Simmons discloses a container as applied to claim 16 above.

Meshberg-Simmons does not disclose a medicament content that is a fluid incorporating a solvent vehicle. Nor does Meshberg-Simmons disclose a medicament content incorporating a pharmaceutically acceptable oily vehicle of monoglyceride, phospholipid, or galactolipid. Meshberg-Simmons also does not disclose an oily vehicle of glycerol mono-oleate, glycerol monopalmitate, or glycerol monostearate. Nor does Meshberg-Simmons disclose a long chain diglyceride, or a fatty acid triglyceride of

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caprylic/capric triglyceride. And Meshberg-Simmons does not disclose a medicament content of calcium mupirocin, fractionated coconut oil, and glycerol mono-oleate.

Henkel et al. discloses a nasal medicament incorporating a solvent vehicle (Page 6, In 20-21), said solvent vehicle comprising a pharmaceutically acceptable oily vehicle (Page 6, In 24) of the group comprising monoglyceride, phospholipid, or galactolipid (Page 5, In 27-30), or of the group comprising glycerol mono-oleate, glycerol monopalmitate, or glycerol monostearate (Page 5, In 35-37). Henkel et al. discloses a long chain diglyceride (Page 5, In 32-34), and a fatty acid triglyceride of caprylic/capric triglyceride (Page 6, In 34-38 and Page 7, In 1-4). Henkel et al. further discloses a medicament content comprising calcium mupirocin (Page 4, In 20-23), fractionated coconut oil (Page 9, In 15-17), and glycerol mono-oleate (Page 6, In 13-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the medicament of Henkel et al. in the container of Meshberg-Simmons in order to apply the treatment of bacterial infection in the nasopharynx directly to the nasal passages as suggested by Henkel et al. (Page 10, In 35-36).

11. Claims 16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Still (US 2,494,456) in view of Simmons.

Regarding claim 16, Still discloses a double walled container (Figure 1) with base wall 17, side walls 10 and 11 extending upwardly from base wall 17 toward upper mouth opening 15, side walls 10 and 11 spaced apart with inner wall 10 and outer wall 11,

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internal cavity 21 containing a medicament content (Col. 1, In 1-4) and bounded in part by inner wall 10. Still discloses base 17 as continuous and linking inner wall 10 and outer wall 11 and closing the space between them.

Still does not disclose inner wall 10 and outer wall 11 made of plastics material, or a label located on the outer surface of the outer wall.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to fabricate the container of Still of plastic material in order to reduce the cost of fabrication. Plastic and glass are common and conventional in the container art.

Still does not expressly disclose a label located on a part of the outer wall, the inner surface of said part not in contact with the medicament content.

Simmons discloses a container label 3 for a container 2 which wraps around the entire outer sidewall of the container (see Figure 2). Simmons teaches the label use for promotional purposes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the container of Still with a label as taught by Simmons in order to promote the sale of the product. As such, the outer label of Still-Simmons would cover the parts of the outer wall in which the inner surface of said part are not in contact with the medicament content, particularly the area above the fluid line (as shown, Figure 1).

As to claim 18, Still discloses side walls in the form of a continuous double wall extending the whole length of the internal cavity.

As to claim 19, the container of Still is cylindrical with concentric and coaxial inner and outer walls.

As to claim 20, Still anticipates upper and lower container parts in Figure 4. with upper inner wall 112 and upper outer wall 114 fitting together with lower inner wall 113 and lower outer wall 115 and forming a seal.

As to claim 21, Still discloses a container having an undisclosed wall thickness. Still does not disclose expressly an inner wall thickness ca. 1-2 mm and an outer wall thickness ca. 1-2.5 mm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to fabricate the container of Still with an inner wall thickness ca. 1-2 mm and an outer wall thickness ca. 1-2.5 mm because applicant has not disclosed that the wall thickness claimed provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with a larger wall thickness because the walls of greater thickness would perform equally well the function of separating the inner and outer walls.

12. Claims 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Still in view of Simmons as applied to claim 16 above and further in view of Henkel et al. Still-Simmons discloses a container as applied to claims 16, and 18-21 above. Still-Simmons does not disclose a medicament content as claimed by the applicant in claims 22-29.

Henkel et al. discloses a medicament content as disclosed above. Henkel et al. further teaches the storage of the medicament content as a kit in a single container with two parts separated by a barrier.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to store the medicament content of Henkel et al. in the container of Still-Simmons as claimed by the applicant and suggested by Henkel et al. in order to provide separate compositions in a single container. The removal of inner lid 12 of Still would allow for mixing the components prior to use.

Response to Arguments

13. Applicant's arguments filed June 2, 2003 have been fully considered but they are not persuasive.

14. The examiner disagrees with the applicant's assertion that Meshberg does not anticipate a label. As stated in the previous Office action, labels are convention in the container art. However the new grounds of rejection render the argument of the location of the label, moot. As the label of Simmons completely surrounds the outer sidewall, the portions of the outer wall, the inner part of which is not in contact with the medicament content, is covered by the label. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The

examiner notes that the applicant's claim does not exclude other portions of the outer wall from contacting the label. Further, claim 16 does not require the sidewalls to be double-walled in their entirety. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

15. In response to applicant's argument that Still fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the space between the inner and outer walls being empty and/or void of medicament content) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Still does disclose a portion of the outer wall which is not in contact with the medicament content (see the area above the fluid line, Figure 1). As the label of Simmons completely surrounds the outer sidewall, the portions of the outer wall, the inner part of which is not in contact with the medicament content, is covered by the label. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Greg Pickett whose telephone number is 703-305-8321. The examiner can normally be reached on Mon-Fri, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

gpr
Gregory Pickett
Examiner
August 11, 2003



Mickey Yu
Supervisory Patent Examiner
Group 3700